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POLICY

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Permits for biotech food shall be re-registered by January 2012

Report Categories:

Biotechnology

Sanitary/Phytosanitary/Food Safety

Agricultural Situation

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Report Highlights:

Russia will require all products accompanied by sanitary-epidemiological conclusions and certificates, including genetically modified products, be re-registered by January 1, 2012, in order to comply with Custom Union regulations.

General Information:

On April 29, 2011, the Russian Federal Service for the Protection of Consumer Rights and Well-Being of Population (Rospotrebnadzor) issued a reminder that business must re-register all previously issued sanitary-epidemiological conclusions and certificates by January 1, 2012, in order to comply with the SPS requirements of the Custom Union (CU). The text of the reminder and information on facilitating re-registration of products that have already been registered in Rospotrebnadzor before July 1, 2010 is in attachments 1 and 2.

The list of commodities subject to sanitary-epidemiological surveillance (control) is specified in Decision 299 of the CU^[i], and updated by other decisions of the Custom Union (No. 341 of August 17, 2010, No. 383 of September 20, 2010, No. 432 of October 14, 2010, No. 456 of November 18, 2010, and No. 566 of March 2, 2011). The most recent version of this list is on the Custom Union website: <http://www.tsouz.ru/db/techregulation/sanmeri/Pages/sanepidem.aspx>. The document stipulates that all food products (in natural or processed form), including those derived from genetically modified organisms, from custom codes 02-05, 07-25, 27-29, 32-34, and 35 are subject to this control (paragraph 1 of Section I of the List). The list also names food and chemical products which are subject to state registration, including the following food products:

1. Mineral water (natural table water, medicinal table water, medicinal water), bottled drinking water, including in packs for baby foods, soft drinks, tonics, alcohol products, including beer;
2. Specialized food products, including baby-food, food for pregnant and milking women, diet food, food for sportsmen, biologically active additives, raw materials for biologically active additives, organic products;
3. Food derived from genetically modified organisms, genetically modified microorganisms;
4. Food additives, complex food additives, flavorings, vegetable extracts as flavor substances, starter cultures of micro-organisms and bacterial starter cultures and technological aids, including enzymes.

Until January 1, 2012, the registration certificates (permits) issued by individual countries, of the CU, remain valid in their country. However, beginning January 2012, only unified CU certificates will be valid on the territory of the Custom Union. Thus, thousands of commodities, which have previously been registered in one of the countries of the CU, need to be re-registered and to receive the unified CU registration certificate by January 1, 2012. The registration body in the Russian Federation is Rospotrebnadzor (Address: build. 5,7, house 18, Vadkovskiy per., Moscow, 127994, Russia; e-mail: depart@gsen.ru ; web-site: www.rospotrebnadzor.ru). The list of applicants for re-registration in Rospotrebnadzor are said to be very long. Thus, at the beginning of May 2011, applicants were able to sign up on a waiting list to filing documents starting on July 2011. The fee is only 200 rubles (\$7) but the length of the process due to the number of submissions is unknown. It is unlikely that the date of re-registration will be extended beyond January 2012. The situation may disrupt trade in some biotechnology food products, which have been registered in Russia previously, and, overall, will slow up registration of new genetically engineered products for food use.

ATTACHMENT 1.

Rospotrebnadzor's Reminder for Re-registration of Sanitary Permits

BEGIN UNOFFICIAL TRANSLATION

The Need for Re-Registration of Permits

The Federal Service for Consumer Rights Protection and Public Well-Being (Rospotrebnadzor) hereby notifies that in accordance with item 31 of the Regulations for the Implementation of Sanitary and Epidemiological Supervision (Control) at the Custom Border and the Custom Territory of the Custom Union (Decision of the Commission of the Custom Union of May 28, 2010) the force of previously issued sanitary-epidemiological conclusions and issued before January 1, 2011 state registration certificates, which confirm the compliance of products with the national requirements, will expire on January 1, 2012.

With regard to the huge number of documents confirming the safety of products issued in accordance with national safety requirements, as well as the need to avoid unnecessary barriers to business after January 1, 2012, we require that all whom it may concern should intensify the filing of applications for renewal of the state Registration Certificates valid for the Custom Union.

If the products are planned for production (imports) after January 1, 2012, it is required to receive a certificate of state registration in accordance with the Unified document confirming the safety of products (goods). This requirement applies to the products included in Chapter II of "The List of Commodities Subject to Sanitary-Epidemiological Surveillance (Control) at the Custom Border and the Custom Territory of the Custom Union."

Registration certificates for the Custom Union confirming the safety of products (goods) to be issued by Rospotrebnadzor or its regional divisions where the previous registration certificates (or sanitary-epidemiological conclusions) were issued.

The said information was sent to the Chamber of Commerce of the Russian Federation, the Russian Union of Industrialists and Entrepreneurs (RSPP), All-Russia Public Organization for Small and Medium Enterprises "OPORA ROSSII".

END UNOFFICIAL TRANSLATION

ATTACHEMNET 2.

Rospotrebnadzor's Instruction to Regional Divisions

BEGIN UNOFFICIAL TRANSLATION

Letter 01/17491-0-32 of 15.12.2010, divisions of Rospotrebnadzor

On the State Registration of Products Evaluated by Rospotrebnadzor before July 1, 2010

In accordance with the Regulation "On the procedure of obtaining of a unified document confirming the safety of products (goods) in terms of its compliance with sanitary-epidemiological and hygienic requirements" approved by the Custom Union Commission on May 28, 2010. № 299, registration certificates (sanitary-epidemiological certificates), issued by Rospotrebnadzor or its regional divisions before July 1, 2010, shall be valid exclusively in the territory of the Russian Federation, within the period of time specified by the certificates, but no later than January 1, 2012.

In case the production (import) of products will continue after January 1, 2012, it is required before that date to get the new certificate of the state registration in accordance with the Unified form of documents confirming safety of products (goods) ^[iii]. This requirement applies to the products included in Chapter II of "The List of Goods Subject to Sanitary-Epidemiological Surveillance (Control) at the Custom Border and the Custom Territory of the Custom Union" approved by the Commission for the Custom Union on May 28, 2010 № 299.

In accordance with the decision of the Commission for the Custom Union of October 14, 2010 № 432, registration certificates ... for the Custom Union for the commodities (goods) that already have the state registration (sanitary-epidemiological conclusion) shall be issued without additional studies (tests) of the products. This does not apply to the products in which previously studied parameters are different from those specified in the "Uniform sanitary-epidemiological and hygienic requirements for goods subject to sanitary-epidemiological surveillance (control)" approved by the decision of the Custom Union Commission No. 299 of May 28, 2010. In such cases only a certain (different) parameter shall be assessed.

To obtain a certificate of state registration in accordance with the Unified form...the following documents shall be provided:

- Application (it shall also contain the number and date of the previously issued registration certificate (or sanitary-epidemiological conclusion);
- The original registration certificate or sanitary-epidemiological conclusion (to be refunded to the applicant);
- Copy of the registration certificate or sanitary-epidemiological conclusion (notarization is not required).
- Document confirming the payment of a 200 RUR fee.

The certificate of state registration in accordance with Unified form ...shall be issued by Rospotrebnadzor or the same regional divisions of Rospotrebnadzor where the previous registration certificate (sanitary-epidemiological conclusion) was issued.

Changes in the National Register for products undergone sanitary-epidemiological certification or state registration are not required.

Information on state registration shall be entered into the Register for Registration Certificates issued in accordance with Unified form of documents confirming safety of products (goods).

This procedure does not apply to newly manufactured (imported) products.

Please proceed as described in this letter, and inform institutions involved in economic activity and other stakeholders accordingly.

G.G. Onishchenko
Head of Rospotrebnadzor

END UNOFFICIAL TRANSLATION

^[i] For more information see GAIN Report RS1036 Custom Union Update _Moscow _ Russian Federation_7/26/2010

^[ii] The Unified form is the form valid for the whole territory of the Custom Union.